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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/787,498	03/16/2001	A. Bruno Frazier	6300.96.1	3953

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EXAMINER	
ODLAND, KATHRYN P	

ART UNIT	PAPER NUMBER
3743	7

DATE MAILED: 10/03/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/787,498	FRAZIER ET AL.	
	Examiner	Art Unit	
	Kathryn Odland	3743	

-- The MAILING DATE of this communication appears on th cover sh et with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *26 August 2003* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-28 and 30-53* is/are pending in the application.

4a) Of the above claim(s) *29* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-28 and 30-53* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Response to Amendment

This is a response to the amendment dated August 26, 2003. Claims 1-28 and 30-53 are pending.

Response to Arguments

1. Applicant's arguments with respect to claims 1, 22, 33, 43 and 51 have been considered but are moot in view of the new ground(s) of rejection.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

3. Claims 1-28 and 30-32 and 51-53 are rejected under 35 U.S.C. 103(a) as being unpatentable over Allen et al. in US Patent No. 6,334,856 in view of Ozbay et al. in US Patent No. 5,406,573.

Regarding claims 1-21, Allen et al. disclose a microneedle array having a substrate with a substantially planar surface, as recited in column 4, lines 30-40; a plurality of hollow non-silicon microneedles on the planar surface of the substrate, each microneedle having a microchannel therethrough that provides communication between at least one input port at a proximal end of each of the microneedles and at least one output port at an opposite end that extends beyond an edge of the substrate, as recited in column 4, lines 40-67, column 5,

lines 1-38, and seen in the figures; microneedles each with a bottom wall, two side walls, and a top wall that define a microchannel, as recited in column 5; a bottom wall that is formed at least partially on top of the planar surface of the substrate and the side walls and top wall are formed around a removable molding material, as recited in columns 9-15, especially column 9, lines 45-67, column 10, lines 42-67, column 15, lines 12-30, and seen in the figures; microneedles that are a two dimensional array, as recited in column 10, lines 43-57; microneedles that are a three dimensional array, as recited in column 21, lines 18-25 and column 22,lines 5-8; microneedles that are aligned substantially parallel to each other on the substrate, as seen in the figures; distal ends of each microneedle that extends beyond the edge of the substrate a distance from about 10um to about 100mm, as recited in column 5, lines 37-58 and column 9, lines 1-33; microchannels in each microneedle that has a cross-section area in the range from about 25um^2 to about 5000um^2, within the scope of that recited in column 5, lines 37-58 and column 9, lines 1-33; lengths of each microneedle that is from about 0.05um to about 5mm, and a width of each microneedle is that from about 0.05um to about 1mm, as recited in column 5, lines 49-57, column 8, lines 65-67, and column 9, lines 1-32; center-to-center spacing between individual microneedles that is from about 50um to about 200um, as recited in column 5, lines 48-52; a substrate the is a material selected from the group of glass, semiconductor material, metals, ceramics, plastics, and composites or combinations thereof, as recited in column 4, lines 32-40; microneedles that are

composed of materials selected from the group of metals, plastics ceramics, glass, carbon black, and composites or combinations thereof, as recited in column 4, lines 40-58; microneedles that are composed of metal materials selected from the group of nickel, copper, gold, palladium, titanium, chromium, and alloys or combinations thereof, as recited in column 4, lines 40-58; microneedles that can withstand flow rates of up to about 1.5 cc/sec, as seen in column 24, Table 2; a coupling channel member that is composed of the same material as the microneedles, as seen in the figures; and a pair of structural support members that mechanically interconnect the microneedles and that precisely control penetration depth of the microneedles, as recited in column 8, lines 50-67.

Allen et al. disclose the invention as claimed with the exception of explicitly reciting: microneedles that are located on the major surface of the substrate such that the microneedles extend in a direction substantially parallel to the major surface; a three dimensional array that has a plurality of two dimensional arrays with spacers therebetween; a three dimensional array that is bonded together by a material selected from the group consisting of molding materials, polymeric adhesives, and combinations thereof; microneedles with a plurality of input ports; or microneedles with a plurality of output ports.

On the other hand, Ozbay et al. teach arrays that are located on the major surface of the substrate such that the they extend in a direction substantially parallel to the major surface, as recited in columns 12-19 and seen in figure 1

and a three dimensional array. Therefore, it would be obvious to one with ordinary skill in the art to modify the invention of Allen et al. to orient the arrays on the surface of the substrate such that they extend in a direction substantially parallel to the major surface for the purpose of ease of manufacture and transportation. Further it would be obvious to one with ordinary skill in the art to further modify the invention of Allen et al. to have a three dimensional array of plurality of two dimensional arrays with spacers therebetween and a three dimensional array that is bonded together by a material selected from the group consisting of molding materials, polymeric adhesives, and combinations thereof. When using arrays it is necessary to use spacers and adhesives are a common bonding method. Furthermore, having a plurality of input and output ports would also be obvious to one with ordinary skill in the art.

With regard to claims, 22-28 and 30-32, Allen et al. disclose a microneedle array device having a plurality of hollow non-silicon microneedles having microchannels therethrough that provide communication between at least one input port at a proximal end of each of the microneedles and at least one output port at an opposite distal end; and at least one structural support member that interconnects the microneedles, as recited in column 4, lines 25-67, column 5, column 8 and seen in the figures. For depending claim rejections see corresponding rejection above.

However, Allen et al. do not explicitly recite: a first structural support member that interconnects the microneedles adjacent the proximal end of the

microneedles; a second structural support that interconnects the microneedles adjacent the distal end of the microneedles; microneedles with a plurality of input ports; or microneedles with a plurality of output ports.

On the other hand, given the stacking teaching of Ozbay et al. a first structural support member that interconnects the array adjacent the proximal end of the array and a second structural support that interconnects the array adjacent the distal end of the array is shown in figure 1 with the alternating layers. Therefore, it would be obvious to one with ordinary skill in the art to modify the invention of Allen et al. to provide a first structural support member that interconnects the microneedles adjacent the proximal end of the microneedles and a second structural support that interconnects the microneedles adjacent the distal end of the microneedles for the purpose of ease of manufacture, enhanced durability and ease of transport. Furthermore, having a plurality of input and output ports would also be obvious to one with ordinary skill in the art.

Regarding claims 51-53, Allen et al. disclose a method of fabricating a microneedle via providing a substrate with a substantially planar surface; depositing a metal material on the planar surface to form one or more bottom walls for one or more microneedles; coating a top surface of one or more bottom walls with a photoresist layer to a height to correspond to a selected inner height of a microchannel for the one or more microneedles; depositing a metal material to form side walls and a top wall upon the one or more bottom walls around the photoresist; removing the photoresist layer from the one or more channels;

depositing via an electroplating process; and a metal that is selected from the group of palladium, titanium, chromium, gold, copper, and alloys thereof, as recited throughout the disclosure.

However, Allen et al. do not explicitly recite: microneedles that are formed on the major surface of the substrate such that the microneedles extend in a direction substantially parallel to the major surface.

On the other hand, Ozbay et al. teach arrays that are located on the major surface of the substrate such that the they extend in a direction substantially parallel to the major surface, as recited in columns 12-19 and seen in figure 1 and a three dimensional array. Therefore, it would be obvious to one with ordinary skill in the art to modify the invention of Allen et al. to orient the arrays on the surface of the substrate such that they extend in a direction substantially parallel to the major surface for the purpose of ease of manufacture and transportation.

4. Claims 33-50 are rejected under 35 U.S.C. 103(a) as being unpatentable over Allen et al in US Patent No. 6,334,856 in view of Lin et al. in US Patent No. 5,855,801.

Regarding claims 33-42, Allen et al. disclose a microneedle device having a substrate with a substantially planar surface; a hollow non-silicon microneedle on the planar surface of the substrate, the microneedle having at least one microchannel therethrough that provides communication between at least one input port at a proximal end of the microneedle and at least one output port at an opposite distal end that extends beyond an edge of the substrate, as recited in

column 4, lines 25-67, column 5, column 8, and seen in the figures; a structural support that is adapted to mechanically fix the microneedle to a surface that is penetrated by the microneedle as recited in column 8; and a plurality of microchannels, necessary for the array. For depending claim rejections see corresponding rejection above.

However, Allen et al. do not show: a *single* hollow microneedle on the planar surface of the substrate; a proximal end having plurality of input ports; or a distal end having a plurality of output ports.

On the other hand, Lin et al. teach a single hollow microneedle, as seen in figure 1A. Therefore, it would be obvious to one with ordinary skill in the art to modify the invention of Allen et al. to have only a single hollow microneedle as taught by Lin et al. for the purpose of a single application with a single injection. Furthermore, having a plurality of input and output ports would also be obvious to one with ordinary skill in the art.

With regard to claims 43-50, Allen et al. disclose a microneedle having a hollow elongated shaft composed of a non-silicon material, the shaft defining at least one microchannel therethrough and having a proximal end and a distal end; at least one input port at the proximal end of the shank and at least one output port at the distal end, the microchannel providing communication between the at least one input port and the at least one output port, as recited in column 4, lines 25-67, column 5, column 8, and seen in the figures; a plurality of microchannels, necessary for the array; a structural support to control penetration depth, as

recited in column 8; and a structural support that is adapted to mechanically fix the microneedle device to a surface that is penetrated by the elongated shaft, as recited in column 8. For depending claim rejections see corresponding rejection above.

However, Allen et al. do not show a *single* hollow elongated shaft on the planar surface of the substrate; a proximal end having plurality of input ports; or a distal end having a plurality of output ports.

On the other hand, Lin et al. teach a single hollow elongated shaft, as seen in figure 1A. Therefore, it would be obvious to one with ordinary skill in the art to modify the invention of Allen et al. to have only a single hollow elongated shaft as taught by Lin et al. for the purpose of a single application with a single injection. Furthermore, having a plurality of input and output ports would also be obvious to one with ordinary skill in the art.

Conclusion

5. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure are as follows:

Chun, K. et al. Fabrication of Array of Hollow Microcapillaries Used for Injection of Genetic Material into Animal/Plant Cells, Volume 38, Issue 3, 1999.

Tonucci, B et al. Nanochannel Array Glass, Science Vol. 258 October 1992.

6. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP

§ 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kathryn Odland whose telephone number is (703) 306-3454. The examiner can normally be reached on M-F (7:30-5:00) First Friday Off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Henry A Bennett can be reached on (703) 308-0101. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1113.

Henry Bennett
Supervisory Patent Examiner
Group 3700

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